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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2002P–0506 and 2003P–0021]

Determination That Hyaluronidase For Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that hyaluronidase for injection (Wydase) was not withdrawn from sale for reasons of safety or effectiveness. While this determination will allow FDA to approve abbreviated new drug applications (ANDAs) for hyaluronidase for injection, in considering whether to file an ANDA for this product, future applicants are advised that such an application raises complex issues regarding the characterization of the active ingredient.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously

approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Lachman Consultant Services, Inc., submitted a citizen petition dated December 5, 2002 (Docket No. 02P–0506/CP1), under 21 CFR 10.30 to FDA requesting that the agency determine whether hyaluronidase for injection was withdrawn from sale for reasons of safety or effectiveness. On January 8, 2003, Amphastar Pharmaceuticals, Inc., submitted a citizen petition (Docket No. 03P–0021/CP1) requesting the same action. On July 15, 2003, Merchant-Taylor International, Inc. (MTI), on behalf of Hyalozyme Therapeutics, Inc., filed a comment to both citizen petitions requesting that FDA determine that

hyaluronidase for injection was withdrawn from sale for reasons of safety and effectiveness. Hyaluronidase for injection is the subject of approved NDA 6–343, formerly held by Wyeth Pharmaceuticals, Inc. (Wyeth), now held by Baxter Healthcare Corp. Hyaluronidase for injection is a protein enzyme and is a preparation of highly purified bovine testicular hyaluronidase used to increase the absorption and dispersion of other injected drugs. Wyeth ceased manufacture of hyaluronidase for injection in December 2001, and it was moved from the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book.

FDA has reviewed its records and the comment filed by MTI and, under § 314.161, has determined that hyaluronidase for injection was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list hyaluronidase for injection in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to hyaluronidase for injection may be approved by the agency; however, FDA recommends that in considering whether to file an ANDA for this drug product, future applicants be advised that such an application is likely to raise complex issues regarding the characterization of the active ingredient under section 505(j) of the act (see docket on conjugated estrogen drug products, Docket No. 98P–0311).

Dated: 10/24/03
October 24, 2003.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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